FEB 1 8 2005

K043439

Special 510(k): Device Modification
Infinity Modular Monitors with VF5 Software

510(k) SUMMARY

as required per 807.92(c)

Submitters Name, Address:

Draeger Medical Systems, Inc.
16 Electronics Avenue
Danvers, MA 01923
Tel: (978) 907-7500
Fax: (978) 750-6879
Contact person for this submission: Penelope H. Greco
Regulatory Submissions Manager
Date submission was prepared: December 6, 2004

Trade Name, Common Name and Classification Name:

Trade Name: INFINITY Modular Monitors with VF5 Modifications (Delta/Kappa/Delta XL/Vista XL/Gamma X XL and SC 7000/8000/9000XL)

Common Name, Classification Name, Class and Regulation Number:

Common Name	Product Code	Class	Regulation Number
Monitor, Physiological, Patient (with Arrhythmia Detection or Alarms)	MHX	II	870.1025
Arrhythmia Detector & Alarm	74DSI	II	870.1025
System, Network and Communication, Physiological Monitors	MSX	II	870.2300

Legally Marketed Device:

Infinity Modular Monitors	K033694
Infinity MIB	K033807

Description of Device Modifications:

Software version VF5 is the latest release of the Infinity Modular Monitors, including the Infinity Vista XL and Gamma X XL (variants of the SC 7000 and Delta monitors) that supports direct connection to the Scio gas module, display of data received from the Infinity BisX and Infinity Trident NMT pods, as well as other minor software modifications. In addition, new devices have been tested for use with the Infinity MIB Protocol converter. Testing in accordance with internal design control procedures has verified that the Infinity Modular Monitors and the Infinity MIB Protocol Converter with VF5 modifications are as safe and effective as submitted in 510(k) K033807 and K033694.

Intended Use:

The Infinity Modular Monitors are intended for multi-parameter patient monitoring. The devices will produce visual and audible alarms if any of the physiological parameters monitored vary beyond preset limits and timed or alarm recordings will be produced. These devices will connect to an R50 Bedside recorder, either directly or via the Infinity Network.

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Assessment of non-clinical performance data for equivalence: Verification and validation testing performed indicates that the modifications implemented with software version VF5 are as safe and effective as previous versions and have not altered the fundamental technology of the device(s).

Assessment of clinical performance data for equivalence: Not applicable

Biocompatability: Not applicable

Sterilization: Not applicable

Standards: IEC 60601-1

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 2005

Draeger Medical Systems, Inc.
c/o Ms. Penelope H. Greco
Regulatory Submissions Manager
16 Electronics Ave.
Danvers, MA 01923

Re: K043439
Trade Name: Infinity Delta / Kappa / Delta XL / Gamma X XL / Vista XL with VF5 Software
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II (two)
Product Code: MHX
Dated: December 10, 2004
Received: December 14, 2004

Dear Ms. Greco:

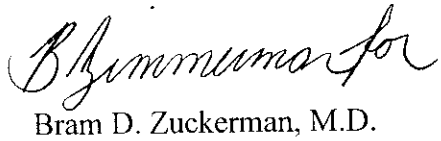
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K043439

Device Name: Infinity Delta / Kappa / Delta XL / Gamma X XL / Vista XL

Indications for Use:

The INFINITY Modular monitors are capable of monitoring:

- Heart rate
- Respiration rate
- Invasive pressure
- Non-invasive pressure
- Arrhythmia
- Temperature
- Cardiac output
- Arterial oxygen saturation
- Pulse rate
- Apnea
- ST Segment Analysis
- 12-Lead ST Segment Analysis
- tcpO2/tcpCO2
- EEG signals
- FiO2

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

B Hammond

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K043439